

**REPORT OF A
GOOD LABORATORY PRACTICE INSPECTION
COMPLIANCE REVIEW AND STUDY AUDITS
CONDUCTED PURSUANT TO THE
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)**

LABORATORY: BioScience Laboratories, Inc.
1765 South 19th Ave.
Bozeman, MT 59718

INSPECTION NUMBER: 20193954997

RESPONSIBLE OFFICIAL: Ms. Amy Juhnke
ajuhnke@biosciencelabs.com
Phone: 406.5875735 ext. 105

DATES OF INSPECTION: June 12 and 13, 2019

SIGNATURES:

Inspector/Auditor: _____
Mark Lehr, Compliance Officer
Office of Compliance/GLP

Administrative/
Technical Reviewer: _____

Approver: _____

SUMMARY

A U.S. Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, Rodenticide, Act (FIFRA) Good Laboratory Practice (GLP) inspection was conducted to determine compliance with 40 CFR 160 and 40 CFR 169.2(k). Three audits were conducted by the inspector. In addition, a GLP compliance inspection was conducted to determine the laboratories current adherence to the GLP regulations. Findings from the FIFRA GLP inspection and study audits are summarized below.

- No negative Findings with respect to GLP issues.

I. INTRODUCTION

A Neutral Scheme FIFRA GLP inspection was conducted at BioScience Laboratories, Inc. on June 12 and 13, 2019 to determine compliance with 40 CFR 160 and 40 CFR 169.2(k). The inspector assigned was Mr. Mark Lehr. Facility information can be found at www.biosciencelabs.com.

II. OPENING CONFERENCE

An opening conference was held beginning at approximately 9:00 am on June 12, 2019. The inspection was led by Mr. Mark Lehr, Chemist, from EPA's GLP Program. Official credentials were presented to Ms. Amy Juhnke, Director of QA upon entry. A FIFRA Notice of Inspection [**Exhibit 1**] was also presented to and signed by Ms. Amy Juhnke.

III. NARRATIVE

The following GLP compliance inspection and study audits were accomplished during the inspection.

GLP Compliance Inspection:

The GLP standards compliance inspection was conducted through interviews with facility personnel and tours of laboratory, archives and test substance / system storage areas. Personnel *curricula vitae* and training records were reviewed, as well as SOPs and equipment calibration/maintenance logs. One ongoing study was selected from the mater schedule as part of the GLP compliance review indicated below:

Evaluation of Hard Surface Disinfectant Formulation for its Viricidal Efficacy

Sponsor: Unit chemical Corporation
7360 Commercial Way
Henderson, NV 89011

Laboratory ID: 1904167.404

- No negative findings with respect to GLP issues

Study Audit:

Three study audits were accomplished through review of available raw data, records, reports, interviews with study personnel and review of laboratory operations. The audit was based on: completeness of raw data, conformance of raw data to study report findings and conclusions, adherence to GLP Standard requirements, appropriate SOPs, and each study's protocol. The following aspects of the studies were reviewed: protocol, raw data, final study report, record keeping, quality assurance, test substance receipt, distribution and administration, and chemical characterization.

The following describe any observations made and activities undertaken during the facility inspection and audit of the studies with respect to the U.S. EPA FIFRA GLP regulations under 40 CFR §160:

A GLP VIRUCIDAL EFFICACY EVALUATION OF A HARD SURFACE DISINFECTANT WIPE

MRID: 50680301

Lab ID: 1806277-404

- No negative findings with respect to GLP issues.

AN EVALUATION OF THE SANITIZING EFFICACY OF ONE TEST FORMULATION FOR USE ON NON-FOOD CONTACT SURFACES

MRID: 506033704

Lab ID: 1602106-204

- No negative findings with respect to GLP issues.

AN EVALUATION OF THE SANITIZING EFFICACY OF ONE TEST FORMULATION FOR USE ON NON-FOOD CONTACT SURFACES

MRID: 506033705

Lab ID: 1706264-204

- No negative findings with respect to GLP issues.


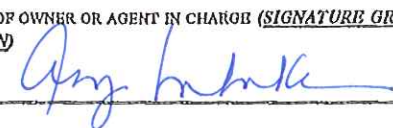
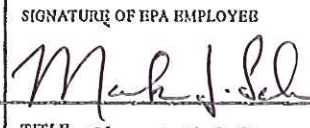
IV. EXIT DISCUSSION

The exit conference was held Thursday June 13, 2019 by Mark Lehr to review findings and recommendations of the FIFRA GLP standards inspection and data audits. Inspection Observations form [Exhibit 2] was completed and copied for the facility providing written indication of the inspector's observations discussed during the inspection and closing conference.

A FIFRA Receipt for Samples [Exhibit 3] was provided to the facility for documents obtained during the inspection.

V. EXHIBITS

Exhibit 1	FIFRA <u>Notice of Inspection</u>	(1 page)
Exhibit 2	<u>Inspection Observations form</u>	(1 page)
Exhibit 3	FIFRA <u>Receipt for Samples</u>	(1 page)
Exhibit 4	Closing Conference Sign-in Sheet	(1 page)

 <p align="center">U.S. ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">GOOD LABORATORY PRACTICE NOTICE OF INSPECTION</p>		ADDRESS (EPA Office) Box 25227 Denver Federal Center, Denver Colorado 80225	
		DATE 6/12/19	HOUR 9:01 AM
FIRM NAME BioScience Laboratories, Inc.		FIRM ADDRESS (NUMBER, STREET, CITY, STATE AND ZIP CODE) 1765 South 19 th Ave. Bozeman, MT 59718	
NAME OF OWNER OR AGENT IN CHARGE Amy L. JUHNKE			
SIGNATURE OF OWNER OR AGENT IN CHARGE (<u>SIGNATURE GRANTS CONSENT TO INSPECTION</u>) 		SIGNATURE OF EPA EMPLOYEE 	
TITLE Dir. of QA		TITLE Chemist/ C.O.	
REASON FOR INSPECTION:			
<input checked="" type="checkbox"/> FOR THE PURPOSE OF PERFORMING AN INSPECTION PURSUANT TO THE GOOD LABORATORY PRACTICE STANDARDS SPECIFIED IN SECTION 40 CFR PART 160			
<input checked="" type="checkbox"/> FOR THE PURPOSE OF INSPECTING AND OBTAINING COPIES OF THOSE RECORDS SPECIFIED IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, SECTIONS 8 and 12(a)(2)(B), AND IN SECTION 40 CFR PART 160.			
<input type="checkbox"/>			
<input type="checkbox"/>			
VIOLATION SUSPECTED: None, Neutral Scheme			



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Box 25227 DFC
Denver Co. 80225

DATE

6/13/19

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO:

Ms. Amy Juhnke

INVESTIGATION ID NUMBER

20193954997

FIRM NAME AND ADDRESS:

Bio Science Laboratories, Inc.

FACILITY INSPECTED ADDRESS

1765 South 19th Ave.
Bozeman, MT 59718

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Audit of 3 studies submitted to EPA: MEID 50680301, 506033704, 506033705
And an ongoing study protocol # 1904167.404.
• No negative findings with respect to GLP issues.

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT

THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE



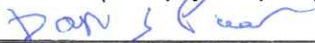
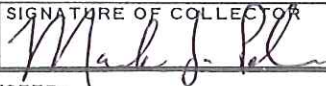
TITLE

COO / PRESIDENT

PREPARED BY:

TITLE

Chemist / C.O.

 U.S. ENVIRONMENTAL PROTECTION AGENCY		ADDRESS (EPA Regional Office) Box 25227, Bldg. 25 Denver Federal Center Denver, CO 80225	
RECEIPT FOR SAMPLES		DATE 6/13/19	
NAME OF INDIVIDUAL Ms. Amy Tuhake		TITLE Director of QA	
FIRM NAME Bio Science Laboratories, Inc.		ADDRESS (Street, City, State and Zip Code) 1765 South 19 th Ave. Bozeman, MT 59718	
SAMPLE NUMBERS			
SAMPLES COLLECTED (Describe fully, List Registration, Lot, Batch, Model, Serial Numbers and other positive identifications.) The following samples were collected by the U.S. Environmental Protection Agency and receipt is hereby acknowledged pursuant to Section 9.(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 g). This section is quoted on the reverse of this form. 1. Protocol #1904167.404 (9 pages) 2. E-mail from Lok Chan to Kelly Birmingham May 30, 2019 (1 page) 3. Floor Plan BSL 11/13/18 (2 pages) 4. BSL org. Chart (1 page)			
			
ACKNOWLEDGMENT OF PRODUCER/REGISTRANT The undersigned acknowledges that the samples shown above were obtained from pesticides or devices that were packaged, labeled, and released for shipment.			
SIGNATURE (Owner, Operator, or Agent) 		TITLE (Owner, Operator or Agent) CEO/ PRESIDENT	
<input type="checkbox"/> DUPLICATE SAMPLES REQUESTED AND PROVIDED <input type="checkbox"/> DUPLICATE SAMPLES NOT REQUESTED		SAMPLES WERE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED	
AMOUNT PAID FOR SAMPLES \$ _____			
<input type="checkbox"/> CASH <input type="checkbox"/> VOUCHER <input type="checkbox"/> TO BE BILLED			
NAME OF COLLECTOR (Print or type) Mark J. Lehr		TITLE OF COLLECTOR Chemist/ Inspector	
SIGNATURE OF COLLECTOR 			

Sign-In Sheet

Company Name and Address: Bioscience Laboratory, Inc.
1765 South 19th Ave.
Bozeman, MT 59718

Attendance for OPENING / CLOSING conference

[illegible]